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DE RUEHSL #0066/01 0461334
ZNR UUUUU ZZH
P 151334Z FEB 08
FM AMEMBASSY BRATISLAVA
TO RUEHC/SECSTATE WASHDC PRIORITY 1517
INFO RUCPDOC/DEPT OF COMMERCE WASHDC PRIORITY

UNCLAS BRATISLAVA 000066

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USDOC FOR 4232/ITA/MAC/EUR/MROGERS
USDOC FOR ITA/MAC/OIPR FOR CPETERS
STATE FOR EEB/TPP/IPE JBOGER

E.O. 12958: N/A
TAGS: KIPR ETRD ECON LO
SUBJECT: 2008 SPECIAL 301 REVIEW FOR SLOVAKIA

REF: A. SECSTATE 9475

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¶1. Summary and Recommendation: Protecting pharmaceutical patent rights has been an ongoing battle requiring regular Embassy attention since Slovakia was removed from the Special 301 Watch List in 2006. There have been two attempts to water-down or eliminate the hard-won patent linkage amendment in the past year, both of which have failed. The Slovak government (GOS) passed new reimbursement legislation in December 2007, which the local PhRMA association argues further hinders market access for their products through arbitrary and non-transparent procedures for setting prices and reimbursement rates. This new Reimbursement Act also allows generic companies to receive pricing and reimbursement approval in advance of patent expiration, which could create an opening for possible patent infringement due to the lack of a set link between the committees making these decisions and the Patent Office. We do not recommend including Slovakia on the 2008 Special 301 Watch List, as has been recommended by PhRMA, but we would like to take advantage of the April Special 301 announcement to send a strong message to the GOS that we continue to have concerns about its commitment to protecting pharmaceutical patent rights. The demarche could specifically encourage the Health Ministry to issue a decree clearly defining the link between pricing and reimbursement approval for generic products and the patent expiration date for the original product. End summary and recommendation.

PATENT LINKAGE THREATENED, BUT PROVISION REMAINS

¶2. Slovakia was removed from the Special 301 Watch List in 2006 and was not recommended for inclusion in 2007 in recognition of the significant progress the country had made in addressing outstanding pharmaceutical patent concerns. In particular, the GOS passed legislation in May, 2006 that created a formal link between the Drug Control Authority (SUKL) and the Industrial Property Office (Patent Office) to ensure that patent-infringing drugs would not be given market access. The patent linkage legislation came under threat two times in the past year, and was only defeated through the concerted efforts of the Embassy and the American Chamber of Commerce's Local Area Working Group (LAWG), the local PhRMA association.

¶3. The debate over the patent linkage amendment was first reopened in Spring 2007 after a Slovak Parliamentarian with business ties to the largest Slovak generic pharmaceutical manufacturer introduced an amendment to the patent linkage provision (Reftel B). The generic industry argued that the

2006 amendment contravened European Commission directives in that it delayed generic entry to the market by not allowing them to begin the registration process in advance of patent expiration. LAWG and the Ministry of Health brokered a compromise amendment that allowed generic producers to take all of the necessary steps to register a drug in advance of patent expiration, while ensuring that the generic version of the drug did not come onto the market before the patent expired. The new compromise amendment, which protected the concet of patent linkage, was approved by Parliament and signed into law on July 1, 2007.

¶4. The second challenge to patent linkage came directly from the Ministry of Health (MOH) less than a month later, when it introduced an amendment that would eliminate the recently-approved patent linkage provision altogether. The provision was buried in an unrelated amendment to the law on health care reimbursement and was circulated for inter-ministerial comments at the beginning of the traditional summer vacation. A strongly-worded letter from the Ambassador and the direct intervention by visiting Commerce A/S Hernandez led the Health Minister to remove this provision from the legislation.

INNOVATIVE COMPANIES REMAIN UNDER THREAT

¶5. The Reimbursement Act, without the provision to remove patent linkage, was passed by the Parliament in December ¶2007. LAWG argues that the new legislation hinders market access by reducing the flexibility in setting reimbursement prices and failing to provide a transparent process for companies to appeal government decisions regarding pricing and reimbursement. LAWG is also concerned, based in large part on the repeated attempts in recent years to eliminate the patent linkage amendment, that the new law creates an opportunity for generic companies to potentially infringe patent rights. Although the law still does not allow generic marketing authorization to become effective while the original product is under patent protection, the Reimbursement Act now allows generic companies to receive pricing approval and be placed on the government's reimbursement list before the generic's marketing authorization has entered into force.

¶6. The new reimbursement law and the implementing regulations do not contain specific language to ensure that the pricing and reimbursement committees create a link to the date of patent approval. The Ambassador raised this concern with the Health Minister in advance of the passage of the legislation, and was assured in a November 28 letter from the Minister that "a generic drug may not be entered on the categorization list before the issuance of a final decision on its registration, even where it has been decided on the basis of the categorization procedure that it meets the criteria for entry on the categorization list." Although LAWG views this provision as an unfair trade practice since an innovative product can only begin the price approval and reimbursement process with an effective marketing authorization, the main complaint for the purposes of the Special 301 process is that it creates an opening for a possible patent infringement. LAWG has suggested to Econoff that the IPR component of this issue could be addressed through an MOH decree creating a clear link between the reimbursement and pricing committees and the Patent Office.

CONTINUING DELAYS ON THE STORAGE FACILITY

¶7. As a part of the 2006 Special 301 review process the MOH promised to procure a new secure storage facility for proprietary drug application data. The original plans called for the completion of the facility by last summer, but the project has been repeatedly delayed and will not be completed until 2009, according to the latest MOH estimates. SUKL, which is responsible for the protection of the data, provided temporary security upgrades at the current facility in 2006 in response to Embassy concerns. Emboffs visited the

facility last winter and were satisfied with the improvements, though the lack of space and design of the building make the facility unsuitable over the long-term. We will continue to keep the pressure on SUKL and MOH to ensure that they follow the current timetable and complete the project on time.

NO WATCH LIST, BUT WE NEED TO KEEP THE GOS' ATTENTION

¶8. The annual Special 301 review remains a useful tool for ensuring that the Slovak government continues to adequately protect intellectual property, especially pharmaceutical patents. The pressure to weaken the patent legislation and squeeze innovative companies has been persistent and is unlikely to diminish given the strong and well-connected generic lobby and the government's stated objectives of both reducing the budget deficit and lowering costs in the health sector. Although the new reimbursement legislation creates the possibility for patent infringement due to the lack of a clear link between the reimbursement and pricing committees and the Patent Office, there is no evidence that this will happen. We therefore do not support including Slovakia on the 2008 Special 301 Watch List at this time, as has been recommended by PhRMA. We would like to use this process to send a strong signal to the government, however, and request a Slovak-specific demarche to the GOS to coincide with the announcement of the Special 301 results in April. The demarche could highlight these concerns and encourage the MOH to issue a decree clearly defining the link between a generic product's pricing and reimbursement approval and the patent expiration date for the original drug.
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